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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/625,375	07/23/2003	Deepak Shukla	85507D-W	2354	
7590 10/06/2006			EXAMINER		
Paul A. Leipold			DO, PENSEE T		
Patent Legal S Eastman Koda		ART UNIT	PAPER NUMBER		
343 State Street			1641	···	
Rochester, NY	7 14650-2201		DATE MAILED: 10/06/2006	5	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Α	pplication No.	Applicant(s)				
Office Action Summary			0/625,375	SHUKLA ET AL.				
		E	xaminer	Art Unit				
		P	ensee T. Do	1641				
Period fo	The MAILING DATE of this commu or Reply	nication appear	s on the cover shee	t with the correspondence ad	dress			
WHIC - External after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE MINISTRATE IN LONGER, FROM THE MINISTRATE IN LONGER, FROM THE MINISTRATE IN LONGER IN LONG	MAILING DATE s of 37 CFR 1.136(a) munication. tatutory period will a y will, by statute, cau	E OF THIS COMMU In no event, however, mapply and will expire SIX (6) is set the application to become	NICATION. y a reply be timely filed MONTHS from the mailing date of this color (35 U.S.C. § 133).				
Status					•			
1)⊠	Responsive to communication(s) fil	ed on 03 Augu	ıst 2006.					
2a)□	•		tion is non-final.	•				
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
-,	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposit	ion of Claims							
4)⊠	☐ Claim(s) <u>1-27</u> is/are pending in the application.							
	4a) Of the above claim(s) <u>22-24</u> is/are withdrawn from consideration.							
	Claim(s) is/are allowed.							
·	Claim(s) is/are allowed. Claim(s) <u>1-21 and 25-27</u> is/are rejected.							
7)								
·	Claim(s)is/are objected to. Claim(s) <u>1-27</u> are subject to restriction and/or election requirement.							
•	ion Papers		,	·				
	:							
,	The specification is objected to by the			to butho Everinos				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
11)	ine oath or declaration is objected t	o by the Exam	liner. Note the attac	ned Office Action of form Pi	10-152.			
Priority (ınder 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a)	a) All b) Some * c) None of:							
	1. Certified copies of the priority documents have been received.							
	 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage 							
	•	•		en received in this National	Stage			
application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.								
,	see the attached detailed Office activities	on lor a list of t	the certified copies i	· ·				
Attachmen	t(s)							
	e of References Cited (PTO-892)	DTO 0101		ew Summary (PTO-413)				
	e of Draftsperson's Patent Drawing Review (mation Disclosure Statement(s) (PTO/SB/08)	P1O-948)		No(s)/Mail Date of Informal Patent Application				
	r No(s)/Mail Date <u>3/16/06; 11/14/03</u> .		6) Other:		·.			

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, claims 1-14, 25-27, in the reply filed on August 3, 2006 is acknowledged. The traversal is on the ground(s) that there is a specific characteristic required by the subcombination (group II) is also required by the combination claim of group I. Such specific characteristic is the support of group II, the subcombination. Applicants argue that such support is also required in the combination claims of group I because claim 1 recites that the beads are used in a microarray which is the support. This is found persuasive and claims 15-21 are now rejoined with claims 1-14, 25-27 of group I.

With regard to group III, Applicants traverse based on the ground that group III requires the microarray of claim 15 and for that reason group III should be rejoined as well. This is not found persuasive because the process of group III can be done without the use of such array. The method can be carried out in solution comprising multiple beads encoded with different photochromic compounds to detect multiple analytes of interest.

The requirement is still deemed proper and is therefore made FINAL.

Claims Status

Claims 1-21 and 25-27 are being examined.

All other claims are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite or unclear of the spatial relationship of the bead and the medium.

Claim 1 is also unclear if the bead surface and the medium are spatially related.

Claim 15 is missing the "comprising" language.

Claim 25 seems to recite a Markush group, please use appropriate Markush language, i.e. is selected from a group consisting of A, B and C.

Claim 26 is unclear of the spatially relationship of the light stabilizer and the photochromic compound or the medium, or the surface of the bead.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3, 7-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Leblans et al. (US 2004/0069857).

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Leblans teaches a microcarrier such as polystyrene beads loaded or encoded with photochromic compound such as 1,2-Bis(2-mehoxy-5-phenyl-3-thienyl) perfluorocyclopentene. The microcarriers are functionalized with one or more ligands bound to the surface of the microcarriers. Ligands specifically binds to the target analytes. (see [58], [150]). Regarding claim 2, it is inherent that the microcarrier of Leblans produces a distinct optical signature by acitinic radiation since Leblans teaches the same bead as that of the present invention. Ligands are biological. (see [58]). The optical signature relates to the receptor on its surface. With respect to claims 8, 9, 11, the medium is inorganic or organic, is polymeric, and is polystyrene or poly(methylmethacrylate. ([39]). Regarding claim 12, the optical is fluorescence. (see [52]). Regarding claims 13 and 14, the microcarriers have diameter ranging from 0.5 um to 300 um, or 10 to 90 um. (see [40]). Regarding claim 10, Leblans teaches that the materials which can be used for deposition of codes or photochromic compounds can be amorphous materials (see [50]) which encompass amorphous polymer. With respect to claim 15, Leblans teaches that the microcarriers are arranged in a microarray for high throughput screening assay. (see [087]). Regarding claims 17 and 18, Leblans teaches that the microcarriers are attached to the support of the array via chemical and/or biological interactions. (see [0024]). Regarding claim 16, since the microarray of Leblans are oriented in a certain way, it is inherent that the microcarriers can be randomly or in orderly distributed on the solid support. The solid support is made of microwells. (see [125]). It is conventional that microwells are made up of a polymer.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leblans in view of Chee (US 6,429,027).

Leblans has been discussed above but fails to teach the laydown of microspheres on the support is 100 to a million per squared cm or 10,000 to 1000,000 per squared cm.

Chee teaches a two-dimensional array of microspheres randomly immobilized in wells of a substrate (see figs. 1A, 1B and col. 5, line 2), wherein the concentration of the microspheres can range from a single microsphere to 2 billion microspheres per cm². (see col. 6, lines 1-33). The microspheres bear biological probes in the form of a bioactive agent (i.e. nucleic acid, (see claim 12)) that binds an analyte of interest. The microspheres comprise a dye in the form of chromophores that can be developed to produce a unique optical signature that allows one to visually identify the microspheres and the bioactive agent bound to the microspheres (see claim 5, col. 21, line 25). Chromophores as defined by Chee absorb light and convert the absorbed light into heat, which is a photo initiated process (see col. 2, lines 8-10).

Since Chee uses wells as substrate for the bead array and Leblans also use wells as a microarray support, it would have been obvious to one of ordinary skills in the art coat the wells of the array in Leblans with 1 single microsphere to 2 billion

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microspheres per squared cm as taught by Chee. Furthermore, it would have been obvious to one of ordinary skills in the art to coat microcarriers on wells at such ranges since it has been held that where the general conditions of a claim are disclosed in the prior arts, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 4-6 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leblans in view of Knowles (US 5,585,042).

Leblans has been discussed above but fails to teach the photochromic compound is naphthopyran, and further include a light stabilizer such as a plasticizer, hindered amine or phenol or a quencher; loading on the microcarriers with a mixture of different photochromic compounds; a mixture of photochromic and non-photochromic compounds; and distinct optical signature is produced by controlling a ratio of at least two photochromic compounds, or a ratio of at least one photochromic compound and a non-photochromic compound.

Knowles teaches photochromic naphthopyrans which can be incorporated into polymeric materials such as poly(methyl methacrylate) or polystyrene (see col. 10, lines 30-50). Knowles also teaches mixing stabilizers with photochromic compounds. Stabilizers such as hindered amine, and singlet oxygen quenchers to improve the light fatigue resistance of the photochromic substances (see col. 9, lines19-60). Knowles also teaches that the photochromic naphthopyrans can be incorporated into the polymeric materials or host materials as mixture of photochromic compounds to exhibit a desired resultant color (see col. 7, line 65-col. 8, line 4). The amount of photochromic

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substance or composition should be sufficient to produce a photochromic effect. (col. 8, lines 25-35). Knowles also teaches that compatible dyes can be applied to host along with the photochromic compounds to achieve a more aesthetic result, for medical reasons. (see col. 9, lines 7-10).

It would have been obvious to one of ordinary skills in the art to load the polymeric microcarriers of Leblans with photochromic compound such as naphthopyrans mixed with stabilizer as taught by Knowles so as to improve light fatigue resistance of the photochromic substances. One of ordinary skills in the art would be motivated to combine the two references because both teach that photochromic compounds can be loaded on polymer host or microcarriers and Leblans also teaches using organic photochromic compound and Knowles teaches an organic photochromic compound of naphthopyran. It would have been obvious to one of ordinary skills in the art add a mixture of different photochromic compounds or a photochromic compound and a fluorescent dye (non-photochromic compound) with controlled ratio to the microcarriers of Leblans according to the suggestion of Knowles for a more aesthetic result.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pensee T. Do Patent Examiner September 28, 2006

LONG V. LE (%/6/6/6 SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600